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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,401	01/16/2002	Alfred Pollak	7126-2	8318

35743 7590 10/26/2005

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,401	POLLAK ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2005 and 21 October 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 33-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31 and 33-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *10/21/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

COMMENTS/NOTES

1. The previous office action is moot in view of the action below. In particular, it should be noted that the Examiner and the Attorney discussed the restriction requirement mailed 7/28/05. The restriction will be modified to the following group desired by Applicant: metal support selected from the group consisting of gold, silver, and copper; complex forming metals selected from the group consisting of transition, lanthanide, and actinide metals; targeting moiety is a peptide; and the disease is an oncological disease (cancer). In addition, Applicant will be asked to elect a species. Applicant's elected species will be SEQ. ID NO. 1. Both the Attorney and the Examiner have discussed the modified lack of unity and an office action reflecting the changes will be mailed to Applicant.

Note: Claims 1-31 and 33-49 are pending.

LACK OF UNITY

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous compositions possible comprising a metal support, ligand, and targeting molecule, and their widely divergent meanings, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I. Claims 1-31 and 33-49, drawn to a product, method of making the product, and uses of the product wherein the metal support surface is selected from the

group consisting of gold, silver, and copper; the complex forming metals are selected from the group consisting of transition, lanthanide, and actinide metals; the targeting moiety is a peptide; and the disease is an oncological disease (cancer).

Group II. Claims 1-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is gold; the ligand is NxS4-x wherein x = 0; targeting moiety is SEQ ID No. 1; the disease is an oncological disease; and the disease is assessed by positron emission tomography.

Group III. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is silver; the ligand is NxS4-x wherein x = 1; targeting moiety is SEQ ID No. 2; the disease is a neurological disease; and the disease is assessed by nuclear magnetic resonance imaging.

Group IV. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is copper; the ligand is NxS4-x wherein x = 2; targeting moiety is SEQ ID No. 3; the disease is an inflammatory disease; and the disease is assessed by single photon emission computed tomography.

Group V. Claims 1-15, 17-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Tc; the ligand is NxS4-x wherein x = 3; targeting moiety is bombesin 7-14; the disease is an infection; and the disease is assessed by ultrafast x-ray computed tomography.

Group VI. Claims 1-15, 17-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Re; the ligand is NxS4-x wherein x = 0; targeting moiety is a dopamine receptor; the disease is an oncological disease; and the disease is assessed by positron emission tomography.

Group VII. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Mn; the ligand is NxS4-x wherein x = 1; targeting moiety is a serotonin receptor; the disease is a neurological disease; and the disease is assessed by digital subtraction angiography.

Group VIII. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Fe; the ligand is NxS4-x wherein x = 2; targeting moiety is a nicotinic receptor; the disease is an inflammatory disease; and the disease is assessed by positron emission tomography.

Group IX. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Ni; the ligand is NxS4-x wherein x = 3; targeting moiety is a GABA receptor; the disease is an infection; and the disease is assessed by single photon emission computed tomography.

Group X. Claims 43 and 44, drawn to products a method of preparation of a support surface for manufacturing a complex forming metal labeled agent.

Note: Each of Groups I – IXI are directed to a composition comprising a metal support, ligand, and targeting moiety; a method of generating a complex using the composition; a pharmaceutical composition comprising the composition; a method of detecting the presence or assessing the severity of a disease; a method of radiotherapy of a disease, disorder, or abnormal physical state; a method of detecting/assessing a disease using a specific technique; and a kit comprising the composition.

3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, *this list is not exhausted, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed*. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and the examiner will endeavor to group the same.

4. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the groups of inventions defined in the claims lack a significant metal support-ligand-target combinations qualifying as the special technical feature that defines a contribution over the prior art. The groups of inventions claimed contain a metal support which does not define a contribution over the prior art. The targeting moiety and ligand combinations which are conjugated to the metal support vary extensively and when taken as a whole result in vastly different complexes. In addition, the diseases which the complexes may be used vary extensively. In particular, the complexes may be used for assessing the

severity of oncological diseases, neurological diseases, inflammatory disease, and infections. Also, the diseases may be assessed vary extensively. For example, possible methods of assessing or detecting the presence or severity of the disease include, positron emission tomography, nuclear magnetic resonance imaging, scintigraphy, single photon emission computed tomography, perfusion contrast echocardiography, ultrafast x-ray computed tomography, and digital subtraction angiography. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

5. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

ELECTION OF SPECIES

7. Claims 1-31 and 33-49 are generic to a plurality of disclosed patentably distinct species comprising, for example, numerous possible compositions comprising a metal support, targeting moiety, disease, and complex forming metals. Applicant is required

under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Notes: *Applicant is respectfully requested to identify the following from within the elected Group above: If Groups II-X are elected, Applicant is respectfully requested to identify the metal support, and complex forming metal ion; and if Group I is elected, Applicant is respectfully requested to identify the targeting moiety and the method of imaging (i.e., PET, MRI, etc.). In addition, Applicant is respectfully requested to identify the claims that read upon the elected species.*

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

October 21, 2005